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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,913	10/05/2001	Richard T. Smith	2105.2210	3137

5514 7590 12/04/2002

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

CONLEY, SEAN E

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 12/04/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,913

Applicant(s)

SMITH ET AL.

Examiner

Sean E Conley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2001 and 11 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 33, 45, 56 recite the limitation "the container". There is insufficient antecedent basis for this limitation in the claim. The preamble of the apparatus claims only refers to the intended use of the apparatus, which is not given patentable weight. More specifically, the claims do not recite that the container is part of the apparatus.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taggart (U.S. Pat. 6,209,591 B1).

Taggart discloses a method and apparatus for providing a container product filling in an aseptic processing apparatus. The apparatus and method meets the stringent United States FDA (Food and Drug Administration) requirements and 3A Sanitary standards and Accepted Practices required to label a food product (foodstuffs) as "aseptic". In addition, the apparatus produces a packaging material with at least about a 6 log reduction of *Bacillus subtilis* var. *globigii* spores using a hydrogen peroxide sterilant vapor with a concentration of about 35% (see column 4, lines 25-41).

More specifically, the invention of Taggart processes containers such as bottles or jars that have a small opening compared to its height and its greatest width (e.g. the ratio of the opening diameter to the height of the container is less than 1.0). In the preferred embodiment, a bottle 12 is formed of a plastic such as polyethylene

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terephthalate (PET). The aseptic sterilant that is used by Taggart is selected from hydrogen peroxide or oxonia, with hydrogen peroxide being the preferred sterilant (see column 4, lines 42-55 and figure 8).

The process delivers the empty bottles to a filler apparatus **50** after passing through a bottle infeed and sterilization apparatus **60** for aseptic sterilization. The bottles **12** in the conveying plate **94** enter an interior bottle sterilization apparatus **116**. A heated hydrogen peroxide vapor fog is introduced into the interior **118** of each bottle **12** (see figures 3 and 10). The application of the sterilant is accomplished with the use of a plurality of sterilant measuring devices **121** and a plurality of probes **123**. Each probe **123** includes an applicator spray nozzle **122**, which provides uniform sterilant application without droplet formation on the interior surface **119** of the bottle **12** (see column 8, lines 17-50). It can be seen in figure 10 that the spray nozzle **122** is positioned through an opening in the container and located just below the shoulder of the bottle and the nozzle has a diameter no great than one-half the diameter of the opening **16**. Also, figure 10 shows that the nozzle **122** is inserted within $\frac{1}{6}$ and $\frac{5}{6}$ the height of the container.

Furthermore, Taggart discloses that a direct spray of heated hydrogen peroxide may be continuously applied to the outside surface **34** of each bottle **12**. A spray nozzle produces the direct spray and a heat exchanger heats the hydrogen peroxide above its vaporization point (see column 6, lines 20-33). Additionally, the probe **123** including the applicator spray nozzles **122** may be positioned immediately above the bottle openings prior to the application of the sterilant (see column 10, lines 28-43).

After the step of applying the hydrogen peroxide vapor to the interior **118** of the bottles **12** the sterilant is purged from the bottles. The purging process introduces a heated gas into the interior of the bottles at a temperature of 131° F and for a time period of about 24 seconds (see column 12, lines 28-67). The temperature is selected based upon the heat resistance for PET bottles and that generally is about 55° C (131° F). The PET bottles may deform when exposed to temperatures above 131° F for extended periods of time. After the bottle is dried, the residual hydrogen peroxide remaining on the bottle **12** surface is less than 0.5 ppm (see column 12, lines 65-67).

The entire process is controlled by a control system **550**, which monitors and controls a spray apparatus **126** that includes the probe **123** and the applicator spray nozzles **122** (see figures 10, 13 and column 10, line 29-42).

The reference to Taggart does not specifically disclose or recite that the nozzle is positioned no closer than 15 mm from any internal surface of the container that is perpendicular to a principal direction of flow of the sterilant vapor from the nozzle.

However, it would have been obvious to one of ordinary level of skill in the art to insert the nozzle into the container and position the nozzle a predetermined optimum distance away from the surfaces being sterilized in order to prevent droplet formation of hydrogen peroxide on the interior surfaces and furthermore, it would have been obvious in view of figure 10 which shows that the nozzle **122** is inserted through the opening **16** of the bottle **12** and is located a distance from the interior surfaces of the bottle.

Also, the reference does not teach a method of removing *Bacillus subtilis* var. *globigii* and *Saccharomyces cerevisiae* spores wherein the reduction by a

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predetermined amount X (log) and Y (log) is effected by the equations recited in the applicants claims 65, 68, 70 and 73.

However, the reference to Taggart teaches a 6 log reduction of *Bacillus subtilis* var. *globigii* spores as required by the applicant and Taggart also teaches the same parameters (temperature and concentration) for hydrogen peroxide sterilization and purging of PET bottles. Therefore, it would have been obvious to one of ordinary level of skill in the art to determine any remaining parameters such as container size, mass of sterilant and humidity in order to sterilize PET bottles because Taggart discloses achieving a 6 log reduction of *Bacillus subtilis* var. *globigii* spores in PET bottles using hydrogen peroxide vapor as claimed by the applicant. Furthermore, it would have been obvious to determine the optimum parameters of temperature, mass of sterilant, humidity, and container volume to sterilize for other organisms that are not taught by Taggart. Additionally, claims 65, 68, 70, and 73 do not require that the equations be used since the equations are not specifically recited as method steps in the method claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Conley, whose telephone number is (703) 305-2430. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920. The Unofficial fax

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phone number for this group is (703) 305-7719. The Official fax phone number for this Group is (703) 872-9310.

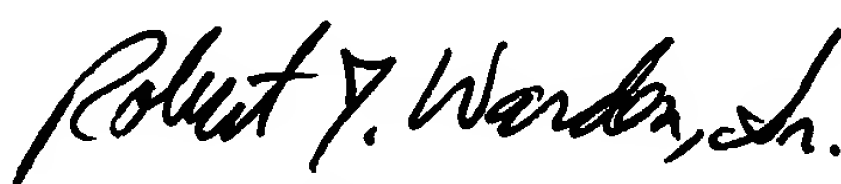
When filing a FAX in Technology Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite the processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [robert.warden@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, whose telephone number is (703) 308-0661.

SEC

November 27, 2002


ROBERT J. WARDEN, SR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700